Partnering in an Uncertain Environment: Consolidation, Integration, and Joint Ventures

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A variety of industry and economic factors continue to motivate health care organizations to invest in strategies aimed at enhancing long-term effectiveness and financial viability. This discussion presents numerous consolidation, integration and joint venture alternatives available to health care organizations, and it identifies the regulatory provisions that should be considered prior to entering any such arrangement.

INTRODUCTION

Many forces continue to push health care providers to collaborate—physicians face (1) declining reimbursement from professional services, (2) challenges in specialty recruitment, and (3) uncertainty in a provider environment that requires greater and greater financial investment to remain financially viable. Hospitals face spiraling costs in the midst of changing payor reimbursement methodologies that put increasing focus on quality of care.

Economic Misalignment

When the Medicare statute was originally enacted, Medicare payment for hospital services was based on hospital-specific costs. Congress replaced this cost-based payment methodology with a prospective payment system (PPS) under which hospitals are paid a predetermined reimbursement under Medicare Part A for inpatient admissions. As a result, hospitals look to cost efficiencies to remain economically viable. In contrast, physicians are paid under Medicare Part B and such payments are encounter-based and are not “capped” like hospital payments under the PPS.

Although physicians control many of the costs of each patient admission, because physicians are paid on an encounter-based system, there are few incentives for them to incorporate cost efficiency into their practices. At the same time, physician investment in ancillary services, such as imaging and ambulatory surgery centers, is also rising. Such services have duplicated hospital investments and further decreased hospital profitability.

The result is a fundamental economic misalignment between hospitals and physicians. This misalignment has caused an ever-increasing tension between hospitals and their medical staffs.

Collaboration Opportunities

These forces cause both hospitals/health systems and physicians to engage in an on-going analysis and review of existing, and possibly new, relationships. The analysis seeks to identify areas where collaboration, combination, and joint ventures may assist in achieving the goals of improved patient care outcomes and quality of care across the inpatient and outpatient care continuum—while achieving stable or enhanced financial results. Hospitals and physicians are exploring mechanisms for joint care delivery that protect the financial viability of physicians and hospitals and produce cost savings and efficiencies for the entire health care system.

The Regulatory Landscape

The two main federal laws used by enforcement agencies in connection with hospital-physician arrangements are the physician self-referral statute (the “Stark law” or “Stark”),¹ which is a civil statute, and the anti-kickback statute (AKS),² which is a criminal law. These laws were
enacted by Congress in large part to ensure that physicians’ health care decisions were based on their professional judgment without financial influence in the form of compensation or other remuneration of others, including hospitals, health systems, medical suppliers, drug, or device manufacturers.

Stark Law

The Stark law prohibits physicians from making referrals to any entity with which the physicians have a financial relationship for a “designated health service” (DHS) payable by Medicare or Medicaid. A DHS is a service “ancillary” to the physician services, including substantially all diagnostic imaging services, lab, and hospital services. Any such direct or indirect financial relationship must fall within an exception to Stark.

Violations of the Stark law have substantial consequences for all parties involved, regardless of the intent of the parties. Sanctions include denial of payment for DHS claims, civil monetary penalties ($15,000 for each claim submitted plus two times the reimbursement claimed), and exclusion from Medicare and Medicaid. In addition, parties who enter into circumvention schemes are subject to a civil monetary penalty of up to $100,000 per violation.

Anti-Kickback Statute

The AKS makes it a criminal offense to knowingly or willfully offer, pay, solicit or receive any remuneration to induce or reward referrals of items or services reimbursable by a federal health care program.

Both parties to a transaction may be considered to be in violation of the AKS. The Office of Inspector General (OIG) has developed safe harbors which, if complied with, give protection to the arrangement. Safe harbor compliance is not required, however, and many joint ventures, contracts and collaborations do not fit squarely within any safe harbors. Those safe harbors which are relied on to protect contractual relationships, such as personal services, and space and equipment leases, all require that the aggregate compensation paid for the service is set in advance and at fair market value. Even where a relationship cannot satisfy all components of a safe harbor, partial compliance may decrease the degree of AKS risk.

In particular, where a “contractual joint venture” is envisioned between providers, it should be carefully structured, taking into consideration the suspicion with which the OIG can view such ventures. Advisory Opinion 04-17 reflects the OIG concern with contractual joint ventures in which physicians bill for services obtained contractually (i.e., through the lease of imaging components) from an entity that could provide the services directly. Factors that increase the chance of OIG scrutiny include: (1) the lessor being an established provider of the service being purchased, (2) the physician bearing little risk, (3) the service being provided to an existing patient base, and (4) the physician buying a turn key arrangement. Even where each element of a contractual joint venture may, on its face, appear to satisfy a safe harbor, the OIG may look at the relationship in totality and not give it safe harbor protection.

A violation of the AKS may result in a felony conviction, fines up to $25,000 and/or imprisonment for up to five years. The OIG and some courts have broadly interpreted the AKS and have generally concluded that it is violated when one purpose of the arrangement is to induce future referrals even if the arrangement is also intended for other legitimate purposes.

Other Laws

In addition to the Stark law and AKS, all collaborations and joint ventures in the health care context should be carefully structured to comply with the complex array of federal and state regulations, including reimbursement rules, civil monetary penalty (CMP) regulations, and antitrust laws, as well as tax-exemption issues, bond financing issues, state law issues (licensing, fee-splitting, anti-self referral, CON), and securities laws.

It is important to note that hospital arrangements with independent physicians in a position to refer patients appear to be under increased regulatory scrutiny. Since the beginning of 2005, it appears that at least a dozen hospitals have reportedly entered into settlements with the OIG to resolve allegedly questionable physician arrangements. Many of these settlements resulted from an investigation by the OIG triggered by a whistleblower associated with the hospital itself.

Collaborations and Joint Ventures—A Range of Options

As providers explore ways to combine to achieve efficiencies and enhanced patient care outcomes while maximizing revenue, they have a continuum of collaboration and venture options to consider.

A legal joint venture is an arrangement involving risk and benefit sharing between organizations, which is created in order to own and operate a common business enterprise. Collaborations that fall short of this definition may include a contractual co-management structure, gain sharing arrangements, leases, professional service agreements, or other
collaborative endeavors, which are discussed below. Full asset mergers, employment, and acquisitions would fall on the other end of the spectrum of integration. Figure 1 graphically presents this spectrum.

**Contractual Models**

Where a collaborative model is under development, legal and/or business considerations may prevent the use of a true equity joint venture. A contractual affiliation may be an attractive alternative to an equity joint venture. A contractual affiliation or collaboration can also be the best first choice. First, it avoids the complexity of creating, owning, and operating a new legal entity. And second, it is a simpler method of achieving a level of integration.

**Management Service Agreements—Clinical Co-Management**

A management services agreement (MSA) may be used in the physician-hospital collaboration context to place certain management responsibilities in one of the organizations over a segment of the operations of the other. For example, a physician group may provide medical management services for a specific hospital inpatient and/or outpatient service line of business, pursuant to a written agreement for fair market value compensation.

In another example, a physician group may manage a hospital outpatient clinic or emergency room for a fixed annual fee, with performance bonuses based on criteria such as (1) improved quality of care, (2) improved patient satisfaction, (3) decreased wait time in the clinics, and/or (4) decreased time for new patient appointments. A result of these efforts should be reduced costs as well as improved clinical outcomes.

The MSA may delegate all management services to the physician group, or it may create a clinical co-management structure in which the physician group and hospital jointly manage a service line or segment of the hospital’s services. The MSA contains quality and performance goals in addition to standard management requirements. Examples are managing a GI service line, cardiology, oncology, or an outpatient surgery center or clinic. A clinical co-management agreement, moves away from the old inpatient-focused model of care delivery where the physician was seen as the customer and hospitals created attractive inpatient settings to enhance the physician’s participation and use of its facilities. The new “co-management” model looks at care delivery from a patient’s perspective—integrating and coordinating inpatient and outpatient services to meet the full spectrum of patient needs. Such a model may create a “virtual entity” within the hospital to create a defined set of clinical services over which the physicians have management responsibilities.

Benefits of a management services model include that the physicians gain substantial input into the operation of the program, with compensation based on satisfaction of quality and programmatic goals.

This model does not involve the creation of a new legal entity or provider and does not require physician equity participation. The model can include noncompete obligations as well. The compensation must be fair market value for the services provided by the physicians, and can be structured to fit within a personal services Stark exception.

Note that if the personal services AKS safe harbor will be used, a percentage-based bonus or penalty will not meet the requirement that the aggregate compensation be set in advance. The agreement may also be structured to satisfy the management contract safe harbor. If equipment or space is involved, those safe harbors should also be explored.

Although under such a management agreement the physicians do not “share” in the cost reductions as they would under a “gain sharing” arrangement (discussed below), this structure has significantly less start-up costs associated with it. The start-up costs include legal and consulting expenses, as well as lower on-going costs. As discussed below, the only OIG-approved gainsharing arrangements involve sophisticated and administratively complex “safeguards” to ensure regulatory compliance with both the CMP as well as AKS. Because the physicians are not paid based on cost savings under a management agreement, but instead receive fixed compensation and incentive compensation based on quality and satisfaction-type indicators, these arrangements carry less regulatory risk and complexity.
Professional Services Agreements

A physician group may also contemplate entering into a professional services agreement (PSA) with a hospital or health system or another group of physicians. Physician groups may join together to jointly recruit a specialist to provide services to both groups where the individual need of each group cannot justify a new hire, but where there are still unmet clinical needs between the groups. Joint call coverage and scheduling between the groups may be included as well.

The groups may also consider entering into a PSA with a hospital or system under which the two physician groups together provide services to the hospital. Where two, or more, groups provide hospital-based services, this can be one method to lock in the site of service, while sharing the responsibility to provide the services. Again, joint call coverage and scheduling can be included. Generally, the physician groups retain the rights to bill for their professional services.

Alternatively, the groups might sell their services entirely to the hospital and permit the hospital or health system to bill for their services under a longer-term PSA. Such a PSA can be an alternative to an employment model under which the physicians can obtain guaranteed community-competitive compensation in return for (1) an exclusive commitment and/or perhaps (2) programmatic leadership and other items that may bring value to the hospital. In all PSA models, the agreement must be at fair market value terms and satisfy a Stark exception as well as address AKS risks, if any.

Gainsharing

The OIG defines gainsharing as any “arrangement in which a hospital gives physicians a percentage share of any reduction in the hospital’s costs attributable in part to the physicians’ efforts.”

Gainsharing can take several forms. Some arrangements are narrowly targeted, giving the physician the financial incentive to reduce the use of a specific medical device or supply, to switch to specific products that are less expensive, or to adopt specific clinical practices or protocols that reduce costs. More broadly designed programs that offer physicians payments to reduce the total average costs per case are more problematic from a regulatory perspective. By giving the physician a share in the reduction in the hospital’s costs attributable to his or her efforts, hospitals predict that the physicians will practice more cost effective and efficient medicine.

As gainsharing involves a hospital making payments to physicians—a financial relationship—it is possible that physicians will refer cases to a hospital with which the physicians have a gainsharing arrangement, a possible Stark violation. Because the Stark law falls outside of the scope of its advisory opinion authority, the OIG has not expressed an opinion as to the Stark law implications. And, while CMS has the authority to issue its own advisory opinions addressing the Stark law, only a handful of Stark advisory opinions have been issued to date, none of which address gainsharing. One should carefully consider application of Stark in developing a gainsharing arrangement. Although there are currently no Stark exceptions specifically tailored to gainsharing, CMS did propose an exception in 2009. The proposed exception included many of the safeguards cited by the OIG in its gainsharing advisory opinion. CMS has not finalized this proposed exception.

Note that because gainsharing payments can’t be set in advance—they are a percentage of cost savings—they don’t fall within safe harbor protections and AKS rules should be analyzed. The OIG has stated that gainsharing may implicate the AKS if one of the purposes of the program is to influence referrals of Medicare business.

Gainsharing programs can also seemingly fly in the face of the Civil Monetary Penalty statute (CMP) which prohibits a hospital from knowingly making a payment to a physician as an incentive to reduce or limit the use of products or delivery of services when treating Medicare or Medicaid beneficiaries under a physician’s direct care. The goal of gainsharing—reducing costs—can be seen as contrary to CMP. This is because reducing costs can be equivalent to reducing care.

Notwithstanding these concerns, the OIG has issued favorable advisory opinions with regard to certain, carefully crafted, gainsharing arrangements. These opinions involved procedures at five hospitals in cardiovascular surgery and cardiology, including interventional cardiology, electrophysiology, and peripheral procedures. Each program made it possible for the hospitals to reward physicians financially for helping the organization achieve cost reductions. In each of these opinions, the OIG declared that it would not impose administrative sanctions because of safeguards that were incorporated into the arrangements.

Approved Programs

The approved gainsharing programs were not simple, or inexpensive, to create or maintain. In each, the hospital implemented a system to track product utilization, procedure cost, and outcomes. With this information, the physicians determined the specific processes they would try to standardize or improve, such as (1) substituting less costly items for more expensive items, (2) standardizing devices, and (3) using or providing services or equipment on an “as needed” basis rather than as a routine matter.
Gainsharing Safeguards
The approved gainsharing programs include safeguards to address OIG concerns regarding the potentially adverse impact on quality of patient care and potential payments to induce referrals. Each program has an outside administrator to oversee the program and ensure quality of care is maintained. Only physicians previously practicing at the hospital may participate in the program, and the program may only include the volumes each physician had at the hospital in the year prior to implementing the program. This also means that new physicians cannot participate in the program. Most of the programs are also limited to one year and only permits the cost savings directly attributable to specific changes in the physicians’ practices set forth in the opinion to be shared with the physicians. In addition, the cost savings are not paid to individual physicians but rather to the group practice to reduce the incentives for individual physicians to reduce care.

Clinical Program Reinvestment
Hospitals have long been able to implement programs under which physicians are not personally paid for costs savings, but which instead dedicate predetermined amounts back into the hospital facility, research, equipment, and technology. This then benefits the physicians and their practice at the hospital.

For example, it has been reported that Evanston-Northwestern Healthcare (ENH) instituted an “orthopedic value improvement initiative” under which ENH entered into new vendor contracts that limited orthopedic surgeons to two vendors for primary Total Joint Replacement components.12 ENH agreed to share 10 percent of the realized savings under the contract with the orthopedic department. These funds were reinvested in a new computer-assisted surgery navigation system and a new motor skills lab. An additional contract created a preferred purchasing arrangement, which allocated more funds (earmarked for new operating room equipment) to the department.

Such programs may provide a much simpler, and less risky, method of “rewarding” changed physician behavior than gainsharing. This is because they do not put dollars in the pockets of physicians. However, for physicians motivated by the quality of equipment and other aspects of the patient-care environment, it can also achieve the same goals of improving quality while reducing costs.

Ownership Models—Legal Joint Ventures
Advances in technology have shifted the provision of many health services from an inpatient to an ambulatory setting. Physicians have been taking advantage of these changing care models and have expanded their ownership into ancillary services and facility ownership, which generates a facility fee. Hospitals and health systems and independent ancillary service providers are interested in joining with these physicians (1) to improve market and financial performance and (2) to strengthen their relationships with the physicians.

Management Service Organization
In an era of increased administrative and practice management expenses, some smaller physician groups are joining together to create a management services organization (MSO). A MSO is commonly formed as a limited liability company and is generally not a provider of health care services. The MSO consolidates the administrative portions of practices to achieve economies of scale. The scope of services may vary and include practice management services, billing, space, equipment, and nonprofessional staff.

The MSO may acquire tangible assets from one or more groups and lease those assets back to the group members on a basis that reflects a fair representation of use by each group. The MSO may spread the acquisition costs of capital among a number of groups and may reduce the overall management time of each participating group. A MSO may achieve a level of administrative reduction, but it does not achieve clinical integration. Because clinical integration is not involved, the regulatory analysis is not as complex. However, AKS concerns must still be addressed to ensure that there is no payment for referrals between the MSO entities. Providers should also be aware of anti-trust concerns. They should ensure that they do not share payor information and other competitive information.

Ambulatory Surgery Centers
Ambulatory Surgery Centers (ASC) continue to be a popular ancillary service operation for physician ownership or for joint ventures. Their popularity is likely to keep growing. The Federated Ambulatory Surgery Association reports that there are currently more than 4,200 ASCs in the United States. CMS recently announced an expansion of the list of Medicare-approved ASC procedures, which will grow to 3,308 in 2008 from 2,500.13 This move will likely expand the ASC market even further.

A jointly owned ASC is commonly formed as a limited liability company with a hospital as the majority owner. Although it is common for physicians to represent minority ownership, the goal of cost savings can be enhanced if the physicians are given a significant voice (if not control over) clinical care matters in the venture. Physicians must
contribute real money, however, to acquire their interest in the ASC. Their referral “stream” cannot be considered an asset or be valued as part of their capital contribution.

Regulations require that the financial terms offered to each investor must be wholly unrelated to referrals or the amount of business generated by the investor in the ASC. In addition, the ASC may not loan or guarantee loan funds to an investor to buy into the ASC. Each investor’s share of profits and losses in the ASC should be directly proportional to the amount of capital invested in the ASC.

Where an ASC joint venture occurs between nonprofit and for-profit entities, the nonprofit should proceed with caution to protect its tax-exempt status and avoid the creation of unrelated business taxable income (UBTI). The structure and operation of the joint venture should be examined to determine (1) whether the joint venture furthers a charitable purpose and (2) whether the arrangement permits the exempt entity to act exclusively in furtherance of its exempt purposes.

The joint venture should be structured, where possible, to be related to the exempt organization’s tax-exempt purposes. As a result, the agreements creating the joint venture must enable the exempt entity to establish that the joint venture (1) serves a community benefit, (2) creates no private increment, and (3) provides private benefit only incidentally to community benefit. Other issues to consider include intermediate sanctions, and issues relating to tax-exempt bonds and property tax exemption.

Despite these regulatory constraints, ASC joint ventures continue to be a popular means to achieve hospital-physician integration and to share in the growing ambulatory service business. One of the reasons that ASC ventures are popular is that they generally can be structured to satisfy the Stark law. Services billed by an ASC under a composite rate are not included in the Stark definition of “designated health service.” Accordingly, if an ASC only provides services that are reimbursable at the composite rate, Stark should not apply to limit or prohibit the physician investment.

**Equipment Joint Ventures**

Where a hospital and physician group are beginning to explore collaborating, or are prohibited from a more comprehensive joint venture due to regulatory challenges, they may enter into an “equipment joint venture” which permits jointly owned equipment (such as a linear accelerator or a magnetic resonance image unit). The equipment is then leased back to the hospital at a fair market value rate. The operating revenue for the technical component remains with the hospital. However, the physicians and the hospital both share in the lease payments as the equipment owners.

Alternatively, the physicians can be the sole owner of the equipment and lease it to the hospital under the terms of a fair market value lease. CMS has had longstanding concerns that per-click and percentage-based compensation may reflect the volume or value of referrals and, therefore, be prone to abuse or be anti-competitive in nature. Previously, special rules on compensation provided that per-click and percentage-based payments were permitted under Stark, so long as the per click or percentage-based amounts were established at fair market value and did not take into account the value or volume of referrals or other business generated. Under the 2009 IPPS Final Rule, however, the Stark exceptions for space and equipment leases were modified to prohibit most per-click and percentage-based lease payments. The indirect compensation exception was likewise modified to incorporate similar language to that of the modified space and equipment lease exceptions. Joint ventures that relied on a per-click structure had to restructure or unwind by October 1, 2009, the effective date of the rule change. Equipment joint ventures need to be thoroughly vetted for AKS compliance as well. This is because of the potential for the physician lessors to profit through referrals to the partner leasing the equipment.

**“Under Arrangement” Transactions**

Another form of joint venture used historically by physicians and hospitals was the “under arrangement” transaction in which a hospital would contract with a third party to provide a hospital service (1) through a contractual arrangement with a physician group or (2) through a joint venture owned by the hospital and the physician group together. This structure was often used with specialized services that require significant capital investment, such as cardiac catheterization laboratories and radiation therapy services. The 2009 IPPS Final Rule, however, expanded the definition of “entity” to include not only the person or entity that bills for the DHS, but also the person or entity that performs the DHS. CMS considers a DHS to have been “performed” by a physician-owned entity if the physician-owned entity does the medical work and could bill for the DHS.

Under the original definition of “entity,” a referring physician could have an ownership interest in an entity that provides services “under arrangements” to hospitals as long as the compensation arrangement between the hospital and the physician-owned entity satisfied the requirements of the indirect compensation exception. Due to the change in the definition of “entity,” if an “under arrangement” service provider performing DHS is wholly owned by physicians or a joint venture with physician ownership, an ownership exception must be
met to allow that physician to make any referrals to the provider. As the ownership exceptions available under Stark are more limited and tend to be more restrictive than the compensation exceptions, many prior “under arrangement” structures had to be restructured or unwound prior to October 1, 2009, the effective date of the rule.

CMS did not fully explain what it means to “perform” DHS under the new “entity” definition. CMS commentary, however, does state that an entity will not be deemed to have “performed” the DHS if:

- the entity only leases or sells space used for the performance of the DHS,
- the entity only leases or sells equipment used for the performance of the DHS,
- the entity only furnishes supplies that are not separately billable but used in the performance of the DHS,
- the entity only provides billing services to the entity performing DHS, or
- the entity only provides personnel to the entity performing the DHS.

CMS has not issued guidance on the number of these services that may be provided by an entity. It is possible that arrangements that only include one or a few of the permitted relationships set forth above may be permitted if properly structured.

**ACQUISITION—COMBINATION MODELS**

The challenging economic conditions are also leading to a renewed interest by physician groups in structurally combining with hospitals and health systems to reduce their economic risk and permit them to focus on patient care rather than the increasingly complex administrative side of their practices. Note that the availability of employment models will depend significantly on state law, corporate practice of medicine, and licensing regulations. Some states continue to prohibit hospitals from directly employing physicians. The models discussed below assume that a nonprofit hospital or system can directly employ physicians. Of course, there are as many models and permutations of models as there are physicians and hospitals. Some of the basic models are discussed below.

**Professional Services Agreement Model**

Where the physicians are not interested in changing their employment home, but are interested in a more closely integrated model, while transferring some financial and capital obligation risk to the hospital, the physician group may (1) retain the ownership of its practice, but sell the equipment and assets to the hospital, (2) transfer the lease or building to the hospital, and (3) sell the services of its employed staff to the hospital under a services agreement. The hospital manages revenue cycle (coding, billing, payer contracting) and may commit certain financial resources to grow the physician’s clinical operations.

The physicians also sell their professional services to the hospital through a PSA that includes initial salary guarantees as well as incentive payments. The hospital may include the physician clinic location in its electronic health records system. At the end of the term, the relationship can be easily unwound as the employment homes of all staff and physicians have not changed, or a full integration may occur. The PSA and management agreement should be at fair market value terms and comply with the fair market value or personal services exceptions for Stark compliance.

**Foundation Model**

A physician group may also sell its practice to a nonprofit affiliate of the health care system, but retain its existing professional association (PA) and remain employed by the PA. Unlike the wholly PSA model, above, the PA here does not retain its clinic staff as employees, but transfers them, along with all of its equipment, assets and goodwill, to the hospital/health system. The PA sells the professional services to the hospital under a long-term PSA. The physicians do not become employees of the hospital or health-system affiliate. They retain benefits and compensation in their own entity. The physicians retain complete control over their own compensation model. The hospital should pay fair market value for the practice and the terms of the PSA should reflect fair market value terms as well.

A variation on this model is that the employment home of the physicians moves to the nonprofit affiliate, which then sells the professional services to the hospital through a PSA. The billing is performed by the hospital affiliate and compensation is paid through the affiliate to the physicians.

**Integrated Subsidiary Model**

Where a physician group is willing to combine more closely with the health care system, it may become a wholly owned or controlled subsidiary of the hospital or health care system. This again permits a sense of autonomy. This is because the group retains a separate corporate entity but the physicians give up day-to-day control of their practice and must comply with all policies of the hospital or system, including compensation models. Again, the sale or transfer of the practice should be at fair market value terms and the compensation of the physicians should satisfy the Stark employee exception.
Physician Enterprise Model
Alternatively, the hospital or system may form a physician subsidiary that is the employment home for all of the hospital’s employed physicians. The physician compensation is governed by that entity and must be consistent with the Stark employee exception. The physicians’ employment home moves to the physician subsidiary, but the PA may be retained through a management services agreement to provide turn-key management services to the subsidiary entity, including administrative, billing, nonprofessional staff, office space, furnishings, and so on.

Fully Employed/Integrated Model
The physicians may also sell their practice directly to the nonprofit hospital or health care system and become employed directly by the hospital. Total physician compensation must be at fair market value to satisfy the Stark employee exception. The models may be more limited due to tax-exempt status concerns of the hospital. The hospital retains all revenues and performs all professional billings. It also retains all financial risk and capital obligations for the practice.

Summary and Conclusion
The environment continues to support further integration, collaboration and combinations in the health care provider industry. Challenging economic times—combined with proposed health care reform—have providers of all shapes and sizes looking for creative ways to achieve cost savings and at least maintain their current economic standing.

The regulatory environment for all forms of combinations is complex. This summary attempts only to highlight the most significant legal issues, but local and state law issues will make some models unavailable, or unattractive, in certain parts of the country. In addition, the regulatory landscape changes continuously so models that work today might become the “under arrangements” models of the future—that is, they may become impermissible under either Stark or AKS. This not only requires vigilance for on-going monitoring of compliance in order to avoid unintentional violations, but it may also inform the negotiating process going into these relationships. Participants should pay particular attention to negotiating the unwind process and procedures today, so that if regulatory changes require a change in relationship, there is an understanding of the process that will be followed in the future.

Notes:
2. 42 U.S.C. 1320a-7(b).
4. 42 U.S.C. 1320a-7(b)(2).
5. See, e.g., United States v. Greber, 760 F.2d 68 (3d Cir. 1985); United States v. Kats, 871 F.2d 105 (9th Cir. 1989).
6. For example, University Hospitals and Healthcare System in Ohio paid the government $83.8 million to resolve allegations that it violated the False Claims Act based on a qui tam relator allegation that the hospital entered into illegal financial relationships with physicians to induce referrals. (See The Department of Health and Human Services and The Department of Justice Health Care Fraud and Abuse Control Program Annual Report for FY 2006). In July 2009, Covenant Medical Center in Waterloo, Iowa, paid the government $4.5 million to settle an allegation of a violation of the Stark law based on an allegation that five employed orthopedic surgeons were paid excessive compensation in order to induce referrals of patients to the hospital, making the physicians among the highest-paid doctors in the country. (As reported by the Chicago Tribune, “Iowa Hospital Pays $4.5 million in Fraud Case,” August 25, 2009).
8. Ibid.
9. 42 U.S.C. § 1320a–7a(b)(1)
10. Special Advisory Bulletin on Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries, 64 Fed. Reg. 37985 (July 14, 1999).
11. OIG Advisory Opinion 01-1; OIG Advisory Opinion 05-1; OIG Advisory Opinion 05-2; OIG Advisory Opinion 05-3; OIG Advisory Opinion 05-4; OIG Advisory Opinion 05-5; OIG Advisory Opinion 05-6; OIG Advisory Opinion 06-22.
12. Gainsharing can add short-term savings, value, American Association of Orthopaedic Surgeons, William J. Robb III, M.D.
14. 42 CFR Sec. 411.354(d).
15. 73 Fed. Reg. 48688.

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